K082353

SEP - 5 2008

510(k) SUMMARY

Fortoss® Vital

Applicant

Biocomposites Ltd
Keele Science Park
Keele
Staffordshire
England
ST5 5NL

Contact Person

Miss Marie Whalley
Tel: +44 (0) 1782 338580
Fax +44 (0) 1782 338599
Email: mw@biocomposites.com

Classification Name:	Bone grafting material, synthetic
Common/Usual Name:	Synthetic Bone Graft Substitute
Trade/Proprietary Name	Fortoss® Vital
Product Code	LYC

Device Description

Fortoss® Vital bone graft substitute is a calcium salt based pre-measured powder and liquid component. The two components are designed to be mixed intraoperatively to produce a homogeneous paste which can then be applied to osseous defects.

The product is provided sterile for single patient use. When Fortoss® Vital is placed in direct contact with viable host bone, new bone grows in apposition to the surface of the implant, filling the pores with new bone during the healing process. As the implant resorbs, bone grows into the space previously occupied by the bone graft substitute.

Intended Use / Indications

The intended use of Fortoss® Vital is for placement in osseous defects to provide a mouldable, resorbable graft in periodontal, maxillofacial and dental implant surgery.

Summary of Technology

The modified Fortoss® Vital has the same technological characteristics as the predicate device and any differences do not raise any concerns regarding safety and effectiveness.

The modified Fortoss® Vital provides a bone graft substitute that resorbs and is replaced with bone during the healing process.

The indications, contraindications, risks and potential adverse events are the same as the identified predicate device and are thus substantially equivalent.

Non Clinical Testing

Data supplied demonstrates that the modified Fortoss® Vital is substantially equivalent to the predicate device and any differences do not raise any concerns regarding safety and effectiveness.

Substantial Equivalence

Documentation provided demonstrates that the modified Fortoss® Vital is substantially equivalent to the legally marketed predicate device in basic features and intended uses. No new concerns have been identified regarding safety and effectiveness of the modified device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Marie Whalley
Biocomposites, Limited
Keele Science Park
Keele Staffordshire
England
ST5 5NL

SEP - 5 2008

Re: K082383
Trade/Device Name: Fortoss® Vital
Regulation Number: 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: II
Product Code: LYC
Dated: August 14, 2008
Received: August 19, 2008

Dear Ms. Whalley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

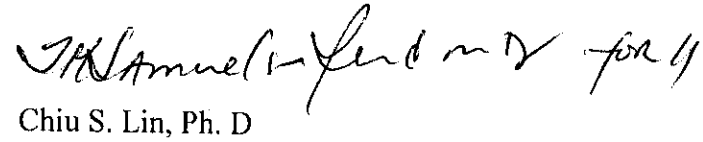
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu S. Lin, Ph. D
Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known):

Device Name: Fortoss® Vital

Indications For Use:

Fortoss® Vital is intended for placement in osseous defects to provide a mouldable, resorbable graft in periodontal, maxillofacial and dental implant surgery.

Prescription Use ✓ OR Over-The-Counter use No
(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K052353